

REMARKS

Claims 1-18 constitute the pending claims in the present application.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the Office Action.

Specification

The Office Action objects to the abstract of the disclosure, because it allegedly does not contain enough information to describe the claimed invention.

Applicants have amended the abstract to further clarify the claimed invention. Reconsideration and withdrawal of this objection are respectfully requested.

Claim rejections under 35 USC §103(a)

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwebel (U.S. Pat. No. 6,270,473) in view of Willis et al. (U.S. Pat. No. 6,406,455).

Specifically, the Office Action alleges that Schwebel teaches a needleless injection device with an ampoule containing a propellant, but fails to reach an ampoule having at least two layers of materials (i.e. two discrete materials). The Office Action further alleges that Willis et al. teach an ampoule having two layers of materials (e.g. one propellant and one passive decay material). Thus, the Office Action concludes, that it would have been obvious to a skilled artisan, at the time of the invention, to modify the teachings of Schwebel by combining it with Willis to have an ampoule with two layers of materials for injection.

While not addressing the merits of this argument, Applicants respectfully point out that Willis is disqualified as a prior art reference under 35 U.S.C. 103(c), since the instant application and the Willis patent (U.S. Pat. No. 6,406,455) were, at the time the claimed invention of the instant application was made, co-owned by Biovalve Technologies, Inc.

Willis was first published as an issued U.S. Patent on June 18, 2002, which is later than the filing date of the instant application (November 30, 2001) and the November 30, 2000 filing date of the four U.S. provisional applications, to which the instant application properly claims benefit under 35 U.S.C. 119(e). (See MPEP 706.02(a)). Therefore, Willis can only qualify as a

prior art, if at all, under 35 U.S.C. 102(e). Pursuant to MPEP 706.02(l)(1), for applications filed after November 29, 1999, subject matter which was prior art under former 35 U.S.C. 103 via 35 U.S.C. 102(e) is disqualified as prior art against the claimed invention if that subject matter and the claimed invention “were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.”

In support of the above statement made pursuant to MPEP 706.02(l)(2), Applicants further submit the USPTO assignment records of the Willis patent (U.S. Pat. No. 6,406,455) and the instant application (U.S.S.N. 10/007,061, or Publication #: US 20020161329 A1).

Pursuant to MPEP 706.02(j), three basic criteria have to be met before a *prima facie* case of obviousness rejection can be made: 1) the prior art references must teach or suggest all the claim limitations; 2) some motivation or suggestion, either found in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine or modify the references must be present; and 3) a reasonable expectation of success is required.

Since the Office Action admits that there is at least one deficiency in Schwebel, and there is no other qualified prior art reference, Applicants submit that the cited art does not teach or suggest all the limitations of the instant application. It naturally follows that there is no reasonable expectation of success for a skilled artisan to arrive at the claimed invention. The issue of combining references is rendered moot because of the disqualification of Willis as prior art. Thus, all three requirements for establishing a *prima facie* case of obviousness have not been satisfied. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. 103(a).

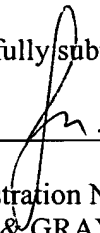
CONCLUSION

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the pending rejections. Applicants believe that the claims are now in condition for allowance and early notification to this effect is earnestly solicited. Any questions arising from this submission may be directed to the undersigned at (617) 951-7000.

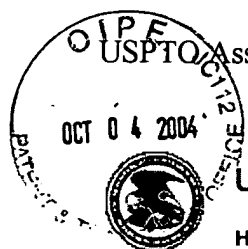
Applicant believes no additional fee is due with this response. However, if an additional fee is due, please charge our Deposit Account No. 18-1945, under Order No. BVTP-P03-007 from which the undersigned is authorized to draw.

Dated: September 28, 2004

Respectfully submitted,

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Total Assignments: 1

Patent #: 6406455 Issue Dt: 06/18/2002 Application #: 09465573 Filing Dt: 12/17/1999

Inventors: JOHN WILLIS, THADDEUS MINIOR, ROBERT GONNELLI

Title: INJECTION DEVICES

Assignment: 1

Reel/Frame: 011046/0756

Recorded: 07/27/2000

Pages: 5

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignors: WILLIS, JOHN

Exec Dt: 03/13/2000

MINIOR, THADDEUS

Exec Dt: 06/29/2000

GONNELLI, ROBERT

Exec Dt: 06/29/2000

Assignee: BIOVALVE TECHNOLOGIES, INC.

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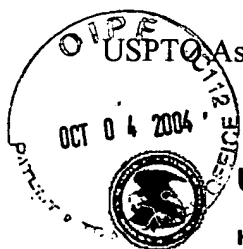
225 FRANKLIN STREET

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Total Assignments: 1

Patent #: NONE

Issue Dt:

Application #: 10007061 Filing Dt: 11/30/2001

Publication #: 20020161329 Pub Dt: 10/31/2002

Inventors: Robert R. Gonnelli, David Lipson, Vasu Nishtala, Ciro Dimeglio

Title: Injection systems

Assignment: 1

Reel/Frame: 013163/0686

Recorded: 10/10/2002

Pages: 6

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignors: GONNELLI, ROBERT R.

Exec Dt: 06/06/2002

LIPSON, DAVID

Exec Dt: 05/13/2002

NISHTALA, VASU

Exec Dt: 06/06/2002

DIMEGLIO, CIRO

Exec Dt: 06/06/2002

Assignee: BIOVALVE TECHNOLOGIES, INC.

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